

REMARKS/ARGUMENTS

With this amendment, claims 35-50 are pending. For convenience, the Examiner's rejections are addressed in the order presented in a January 4, 2006 Office Action.

I. Status of the claims

Claim 41 is amended to be dependent from both claims 35 and 37. Claim 48 is amended to recited 95% identity to residues 1-328 of SEQ ID NO:2. Claims 35-38 and 48 are amended to recite identity over the entire length of the amino acid sequence. Support for these amendments is found throughout the specification, for example at page 9, lines 2-4 and at page 15, lines 22-25. Claims 40 and 50 are amended to recite the epitope sequence DYKDDDK. These amendments add no new matter.

II. Objections to the specification and figure legends

The Office Action objects to the presence of hyperlinks in the specification. In order to expedite prosecution, the specification is amended to remove hyperlinks. The Office Action asserts that SEQ ID NO's are required in the legend of Figure 3. In order to expedite prosecution, the legend of Figure 3 is amended to include SEQ ID NO's.

In view of the above amendments, withdrawal of the specification and drawing objections is respectfully requested.

III. Rejections for alleged obviousness type double patenting

Claims 35-47 and 49-50 are rejected for alleged obviousness type double patenting over claims 1-15 of US Patent No. 6,709,834. Applicants will file terminal disclaimers to overcome these rejections, if appropriate, when the present claims are deemed otherwise allowable.

IV. Claim objections

Claim 40 is objected because of alleged informalities. According to the Office Action, the terms myc, V-5 and FLAG are abbreviations. This is not correct. The terms myc, V-5 and FLAG are commonly used in the art to refer to epitope tags. In support, Applicants submit Exhibit A, Zhang *et al. Nat. Cell. Biol.* 5:578-581 (2003), which demonstrates the usage of the terms in a scientific publication. See, *e.g.*, Figure 1A-C and legend at page 579. However, in order to expedite prosecution, claims 40 and 50 are amended to recite the well-known sequence of the FLAG® epitope tag solely because that term is a trademark.

Claim 48 is objected to because of alleged improper form. In order to expedite prosecution, claim 48 is amended to remove reference to claim 37 and to recite 95% identity to residues 1-328 of SEQ ID NO:2.

In view of the above amendments, withdrawal of the claim objections is respectfully requested.

V. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 35-47 and 49-50 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. According to the Office Action, the specification does not provide description of polypeptides with at least 90-95% identity to SEQ ID NO:2. The Office Action alleges that those of skill would not recognize that the inventors had possession of the claimed invention at the time of filing. The Office Action addresses the analysis to polypeptides that have 90% identity to SEQ ID NO:2. Applicants respectfully remind the Examiner that certain dependent claims are directed to polypeptides that have 95% identity to SEQ ID NO:2 and that those dependent claims should also be considered.

Applicants respectfully traverse the rejection. As currently applied, the specification does comply with US patent law for description of a nucleic acid or amino acid sequence. The Federal Circuit court of Appeals addressed the description adequate to show one of skill that the inventors were in possession of a claimed genus at the time of filing. See, *e.g.*, *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). An applicant may also show that an invention is complete by

... disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Id.* at 1613.

Furthermore, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *See, e.g.*, 66 Fed. Reg. 1099, 1106 (2001). (Although the Office Action cites Interim Written Description Guidelines published in 1998, Applicants believe that the Examiner is well aware that 1998 Guidelines have been superceded by, *e.g.* the Federal Register citation above.)

The specification does provide descriptive support for the full scope of the claimed invention by providing both SEQ ID NO:2, a reference sequence for the claimed polypeptides, and a sialyltransferase assay used to determine whether polypeptides with 90 or 95% identity to SEQ ID NO:2 have the enzymatic activity required by the claims. The assay is described at page 24, lines 11-16 and at page 28, line 7 through page 29, line 2. This information is more than adequate to meet the written description requirement, particularly in view of *Enzo*, cited above, recent Board decisions, and the interpretation of the Written Description Guidelines evidenced by the USPTO's own Synopsis of Application of Written Description Guidelines.

Applicants respectfully bring to the Examiner's attention two recent decisions by the Board of Patent Appeals and Interferences: *Ex parte Sun*, Appeal No. 2003-1993 and *Ex parte Bandman*, Appeal No. 2004-2319. In both cases, the board found that claims directed to sequences with 80% or 95% identity to a reference sequence were described because the supporting specifications provided a single reference sequence and a functional assay for activity of the encoded proteins. Such teachings are included in the present application, as indicated above.

Applicants also direct the Examiner's attention to Example 14 of the Synopsis of Application of Written Description Guidelines, which analyzes a claim directed to a protein with an amino acid sequence at least 95% identical to SEQ ID NO:3 and that has a catalytic activity.

In Example 14, the specification provided one example of a protein that was a member of the claimed genus. The Patent Office concluded that the claim of 95% identity to a reference sequence with a specified catalytic activity was adequately described within the meaning of 35 U.S.C. §112, first paragraph. First, the Synopsis reasons that the genus of proteins that must be variants of the claimed SEQ ID NO:3 does not have substantial variation since all of the members must have 95% identity to the reference sequence and must have the specified catalytic activity. Therefore, according to the Synopsis, the "single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay. . . ." that could be used to identify members of the claimed genus. The specification discloses the sialyltransferase activity of the claimed protein at page 24, lines 11-16 and at page 28, line 7 through page 29, line 2. Thus, at a minimum, on the basis of the Synopsis of Application of Written Description Guidelines issued by the USPTO, the present claims that recite 95% identity to SEQ ID NO:2 meet the written description requirement.

In view of the above arguments and amendments, withdrawal of the rejection for alleged lack of written description is respectfully requested.

VI. Rejections under 35 U.S.C. §102(b)

Claims 35-39 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Gilbert *et al.* *J. Biol. Chem.* 271:28217-28276 (1996).

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found...in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, in order to anticipate, the cited reference must contain every element of the claims at issue.

Applicants respectfully traverse the rejection and submit that, as amended, the claims are not anticipated by the cited reference.

Gilbert *et al.* does not disclose all the element of the claimed invention. Gilbert *et al.* discloses the sequence of *Neisseria* α -2,3-sialyltransferase genes and proteins. The Office

Action alleges this disclosure anticipates the claimed invention because a three amino acid sequence from the *N. meningitides* protein is identical to a three amino acid sequence found in the claimed *C. jejuni* polynucleotide sequence.

Applicants have amended the claims to recite 90% or 95% amino acid identity to a reference *C. jejuni* polypeptide over the entire length of the claimed amino acid sequence. The alleged three amino acid region of identity does not provide 90% or even 95% identity to a reference *C. jejuni* polypeptide over the entire length of the disclosed *Neisseria* α -2,3-sialyltransferase enzyme and thus, does not disclose a claimed sequence. Because Gilbert *et al.* does not disclose a protein with the claimed structural relationship to the reference *C. jejuni* polypeptide, Gilbert *et al.* does not anticipate the claimed invention.

In view of the above amendment and remarks, Applicants respectfully request that the rejections under 35 U.S.C. §102(b) be withdrawn.

V. Rejections under 35 U.S.C. §102(e)

Claims 41-47 are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Paulson *et al.* (U.S. Patent No. 6,399,336). The Office Action alleges that Paulson *et al.* discloses a method of adding a sialic acid residue to an acceptor molecule and that the disclosed method anticipates the claimed invention. Applicants respectfully traverse the rejection.

According to the MPEP, disclosure of a genus does not always anticipate a claim to a species within that genus. (MPEP2131.01). For a chemical genus, one of ordinary skill in the art must be able to "at once envisage" the specific compound within the generic chemical formula. One of ordinary skill must be able to draw the structural formula before a compound can be "at once envisaged."

Paulson *et al.* disclose and claim methods to add sialic acid to an acceptor sugar using a genus of *C. jejuni* α -2,3-sialyltransferase enzymes. While the claims of Paulson *et al.* encompass the claimed enzymes, the reference does not specifically name or disclose them.

Relationship to an appropriate sequence listing, as Applicants have provided here, allows one of skill to "at once envisage" a specific amino acid sequence. The present invention is a method of adding sialic acid to an acceptor sugar using polypeptides with a defined structural

relationship to the CstI enzyme, a specific *C. jejuni* α -2,3-sialyltransferase enzyme. The present invention includes the structure of the CstI protein and patentable variants, *e.g.*, the claimed genus of polypeptides. Thus, the claims at issue are directed to a sub-genus of proteins not specifically named or disclosed in the Paulson *et al.* genus, and as such, are not anticipated by the reference.


In view of the above remarks, Applicants respectfully request that the rejection under 35 U.S.C. §102(e) be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


Beth L. Kelly
Reg. No. 51,868

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
BLK:blk
60762631 v1